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February 12, 2007

February 20, 2007 – **Public Version**

BY E-FILE

The Honorable Gregory M. Sleet
United States District Court
U.S. Courthouse
844 North King Street
Wilmington, DE 19801

Re: Talecris Biotherapeutics, Inc. v. Baxter International Inc. and Baxter Healthcare Corporation, D. Del., C.A. No. 05-349-GMS

Dear Judge Sleet:

Plaintiffs apparently misunderstand the nature of the summary judgment motion Baxter seeks permission to file, wrongly suggesting the motion would be "laden with questions of material fact." To the contrary, Baxter expects to ground its motion on the expert reports and data submitted by Plaintiffs. Plaintiffs' own evidence - with which it surely cannot quarrel - establishes that Plaintiffs cannot meet their burden of proof at trial. Consequently, it serves the interest of judicial economy and justice to allow a summary judgment motion to be filed.[1]

I. Plaintiffs' Data Shows It Cannot Prove Infringement

To prove infringement, Plaintiffs must establish that the solvent/detergent treatment used by Baxter in the process of making GAMMAGARD® Liquid increases anticomplement activity ("ACA"). In its *Markman* Order (D.I. 199) this Court ruled that ACA is "the measure of the ability of antibodies to bind complement" and that one unit of ACA activity is "defined as the amount of protein capable of activating 50% of the complement in an optimally titered complement and red blood cell hemolysin system." *Id.*

[1] For some reason Plaintiffs suggest multiple motions would be filed. That is wrong; Baxter only seeks leave to file a single motion.

Plaintiffs' expert, Michael Carroll, tested in-process samples from Baxter using a hemolysin assay. As shown in Exhibit 3 submitted with Baxter's letter of February 1, 2007, there was no statistically significant increase in ACA after the solvent/detergent treatment.[2] Baxter's test data goes even further, showing that ACA declines after solvent/detergent treatment. Baxter Ex. 5. Plaintiffs have only one contradictory data point using a test that is *not* a hemolysin assay. Baxter Ex. 4. That sole outlier is not sufficient to meet plaintiffs' burden of proof regarding infringement.

In addition, after the solvent/detergent step the '191 patent requires an incubation to reduce ACA "to an acceptable level suitable for intravenous administration." Plaintiffs' own data, however, shows that the ACA level in Baxter's product already was suitable for intravenous administration before incubation. *See*, Ex. 3; *see also*, Ex. 5. Consequently, the Court should entertain Baxter's summary judgment motion.

II. The Patent Lacks Adequate Written Description And Is Indefinite Because, As Plaintiffs' Expert Concedes, There Is No Agreed Definition of "Acceptable" ACA

Knowing this Court precluded arguments regarding indefiniteness during claim construction (D.I. 192), Plaintiffs now seek to preclude those arguments afterward as well. This Court, like others, rightly has refused to impose that Catch-22 on parties challenging the validity of a patent. *Pharmastem Therapeutics, Inc. v. Viacell, Inc., et al.*, 2003 WL 124149, fn.1 (D. Del. 2003) (attached hereto as Baxter Ex. 6); *Harrah's Entertainment, Inc. v. Station Casinos, Inc.*, 321 F. Supp. 2d 1173, 1176 (D. Nev. 2004). Even after a claim term has been construed, it can still be indefinite and render the patent invalid. *Harrah's*, *supra*, at 1178-81 (even when claim term was accorded its "plain meaning" the patent still was invalid for indefiniteness and lack of adequate written description.)

Plaintiffs' expert, Dr. Gelfand, and Baxter's expert, Dr. Kindt, both state there is no agreed definition of "acceptable level" of ACA. Plaintiffs' expert, Dr. Gelfand, admits:

REDACTED

(Gelfand Rebuttal Report, pg. 5 [attached hereto as Baxter Ex. 7]). Indeed, Dr. Gelfand says "acceptability" is determined on a patient-by-patient basis:

REDACTED

[2] For the purpose of this motion Baxter assumes, without conceding, that Plaintiffs accurately used a proper assay. Baxter does not concede any elements of infringement as Plaintiffs rather gratuitously hope. Baxter's motion, however, will focus on this failure of proof by Plaintiffs.

REDACTED

Id.

REDACTED

(*Id.* at 5, 9). This is the very definition of an indefinite claim term. *Honeywell International, Inc. v. International Trade Comm.*, 341 F.3d 1332, 1340-42 (Fed. Cir. 2003) (when a test is required to determine infringement, the manner in which the test is run impacts its outcome, multiple possible tests exist, and the patent does not specify a particular one, the patent is "insolubly ambiguous" and invalid); *Harrah's*, *supra*, 321 F. Supp. 2d at 1179. Indeed, Dr. Gelfand confirms the conclusion of Baxter's expert that Claim 1 is invalid because there is no agreed measure of acceptable ACA:

REDACTED

Id. pg. 6 (emphasis added).

* * * * *

Baxter will not rely on thousands of pages of disputed evidence to support its motion. Rather, Baxter will use Plaintiffs' data and evidence, which it cannot dispute, to prove the '191 patent is invalid and not infringed. Thus, Baxter seeks permission to proceed with its motion for summary judgment.

Respectfully,

/s/ Philip A. Rovner

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PAR/mes/778819
Enc.
cc: Jeffrey B. Bove (by E-mail and hand delivery)
Bradford J. Badke (by E-mail and Federal Express)

EXHIBIT 6

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Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court,
D. Delaware.
PHARMASTEM THERAPEUTICS, INC., Plaintiff,
v.
VIACELL INC., Cryo-Cell International, Inc., Corcell, Inc., Stemcyte, Inc., CBR Systems, Inc. f/k/a Cord Blood Registry, Inc., Birthcells Technology, Inc., Nustem Technologies, Inc., and Bio-Cell, Inc., Defendants.
No. 02-148 GMS.

Jan. 13, 2003.

ORDER

SLEET, J.

***1** After considering the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that the court construes the disputed claims of the patents-in-suit as follows:

U.S. Patent Nos. 5,004,681 and 5,192,553:

1. "hematopoietic stem cells"

"hematopoietic stem cells" is construed to mean "cells capable of effecting repopulation of blood and other hematopoeietic organs."

2. "cryopreservative"

"cryopreservative" is construed to mean "an agent capable of preserving at very low temperatures."

3. "cryopreservation," "cryopreserving," and "cryopreserved"

"cryopreservation," "cryopreserving," and "cryopreserved" are construed to mean "preserving at very low temperatures that may also include an additional agent capable of preserving the cells, blood components, or compositions."

4. "therapeutic composition"

"therapeutic composition" is construed to mean "a composition that is useful for the treatment or prevention of diseases or disorders."

5. "[stem cells] in an amount sufficient"

"[stem cells] in an amount sufficient" is construed to mean "in a quantity as much as is needed." [FN1]

FN1. Consistent with the court's oral ruling during the Markman hearing on January 10, 2003, the court will not address the defendants' indefiniteness argument at this stage of the proceedings. While the court recognizes that a determination of indefiniteness is necessarily intertwined to some degree with claim construction, it is clear that the court must first attempt to determine what a claim means before it can determine whether the claim is invalid for indefiniteness. *See ASM America, Inc. v. Genus, Inc.*, 2002 WL 1892200, *15 (N.D.Cal. Aug. 15, 2002) (recognizing that claim construction must proceed before an indefiniteness challenge); *see also Intervet America, Inc. v. Kee-Vet Labs.*, 887 F.2d 1050, 1053 (Fed.Cir.1989). The court's position at this time does not, however, represent an actual adjudication on the defendants' indefiniteness defense. At present, the court is merely holding that the claim is sufficiently definite to survive claim construction.

Finally, the court wishes to note that the defendants bear the burden of proving invalidity by clear and convincing evidence. *See North American Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed.Cir.1993). The defendants have not, however, filed a motion seeking to invalidate the patents on indefiniteness grounds. Rather, they simply assert their arguments in their opposition claim construction brief. Such an approach is clearly an attempt at an end-run around the court's scheduling order regarding the filing of dispositive motions, and will not be sanctioned.

6. "derived"

"derived" is a commonly understood word and requires no additional construction.

7. "can proliferate within the host"

"can proliferate within the host" is construed to mean "capable of increasing in quantity."

Not Reported in F.Supp.2d, 2003 WL 124149 (D.Del.)

Motions, Pleadings and Filings **(Back to top)**

• 2004 WL 3333208 (Trial Motion, Memorandum and Affidavit) Reply of Stembanc, Inc. in Support of Motion to Dismiss Cbr Systems, Inc.'S First, Second, Third, Fourth, Fifth, and Sixth Counterclaims Pursuant to Fed. R. Civ. P. 12(b)(6) (Dec. 15, 2004)Original Image of this Document (PDF)

• 2004 WL 3333205 (Trial Motion, Memorandum and Affidavit) CBR Systems, Inc.'s Opposition to Pharmastem Therapeutics, Inc.'s Motion to Dismiss CBR Systems, Inc.'s First, Second, Third, Fourth, Fifth, Sixth and Seventh Counterclaims Pursuant to Fed. R. Civ. P. 12(b)(6) (Nov. 19, 2004)Original Image of this Document (PDF)

• 2004 WL 3333201 (Trial Motion, Memorandum and Affidavit) Pharmastem Therapeutics, Inc.'s Motion to Dismiss Defendant CBR's First, Second, Third, Fourth, Fifth, Sixth and Seventh Counterclaims (Sep. 13, 2004)Original Image of this Document (PDF)

• 2004 WL 3333200 (Trial Pleading) Complaint for Patent Infringement (Jul. 28, 2004)Original Image of this Document (PDF)

• 2003 WL 23310808 (Verdict and Settlement Summary) (Oct. 29, 2003)

END OF DOCUMENT

EXHIBIT 7

THIS EXHIBIT HAS BEEN REDACTED IN ITS ENTIRETY